UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,358	03/04/2002	David Tumey	VAC.702.US	3855

60402 7590 02/05/2007

KINETIC CONCEPTS, INC.
ATTN: LEGAL DEPARTMENT INTELLECTUAL PROPERTY
P.O. BOX 659508
SAN ANTONIO, TX 78265

EXAMINER	
HAND, MELANIE JO	
ART UNIT	PAPER NUMBER
3761	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/090,358	TUMEY, DAVID	
	Examiner	Art Unit	
	Melanie J. Hand	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed November 17, 2006 have been fully considered but they are not persuasive.

With respect to applicant's arguments regarding the prior art of Svedman: Applicant argues that Svedman does not teach a capacitive sensor, contrary to the position of the previous Office action. This is correct, however since a specific sensor was not claimed. Examiner has restated the rejection to omit this statement. Applicant further argues that the sensor that is taught by Svedman does not sense fluid compositional characteristics. Examiner disagrees. Svedman teaches temperature sensors. The fluid compositional characteristic claimed in understood from the disclosure to mean a change in the concentration of bacteria in a fluid. Temperature change in a wound fluid directly correlates with change in bacteria count, thus temperature is considered herein to be a fluid compositional characteristic. Examiner has further restated the rejection of claim 1 to reflect this position, however the grounds of rejection are maintained.

Applicants' arguments with regard to dependent claims 2-10 have been fully considered but are not persuasive as Applicants' arguments depend entirely on Applicants' arguments regarding the rejection of claim 1, which have been addressed *supra*.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 4,382,441).

With respect to **Claim 1:** Svedman teaches a device comprising screen means 11 for placement within a wound bed, sealing means 10 adhered over the screen means and thus also over the wound bed. Conduit 12 fluidly connects said screen means 11 to a vacuum source. A fluid compositional sensing device 16 sensing temperature (interpreted herein as a fluid compositional characteristic in that a temperature increase signals the presence of bacterial infection which is a change in composition), is placed in the conduit 12 (i.e. between the screen means and vacuum source) and connected to the regulator member 15 of supply conduit 12 which connects said screen means and sensing device 16 with the vacuum source. (Col. 3, lines 39-42)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Overton et al ('846).

With respect to **Claim 2:** Svedman does not teach that sensing device 16 is comprised of a gas chromatograph. Overton teaches a portable gas chromatograph comprising a photoionization detector (col. 12, lines 23-26). Overton teaches that gas chromatographs are commonly used in the art to rapidly identify the contents of gaseous or liquid samples. Thus since the sensor of Svedman and the gas chromatograph taught by Overton seek to solve a similar problem in the

art of sensing fluid compositional characteristics, it would be obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensing device taught by Svedman with a gas chromatograph as taught by Overton in order to rapidly detect microorganisms/infection in the drainage fluids.

With respect to **Claim 3:** Svedman does not teach a gas chromatograph in optical proximity to a photodiode. A photodiode is a type of photodetector, and since Overton teaches that a detector is a main, known component of a gas chromatograph, and Examiner has stated that it would be obvious to one of ordinary skill in the art to employ a gas chromatograph as a fluid compositional sensing device, it would thus also be obvious to one of ordinary skill in the art to modify the sensor of the combined teaching of Svedman and Overton by employing a photodiode as a viable detector element for the chromatograph.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Lewis et al ('440).

With respect to **Claim 4:** Svedman does not teach that the sensing device 16 comprises a sensor array. Lewis teaches sensor arrays that facilitate detecting more than one condition of, and/or analyte in a fluid, thus facilitating the treatment of a patient or wound site for microorganisms causing infection. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensor taught by Svedman with the sensor array taught by Lewis so as to detect microorganisms causing infection at a wound site in the drainage fluids.

Claims 5, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Henley et al ('109).

With respect to **Claim 5:** Svedman teaches a fluid removal connection 13 but does not explicitly teach that the connection 13 is to a collection canister. Henley teaches a wound treatment apparatus with a bandage assembly that includes a drainage bandage 20, a vacuum source fluidically communicating with the drainage bandage 20 via flexible tube 24, a sensing device 172 or 174 and a collection canister (164 or 166). Henley teaches that the inclusion of the canisters contributes to the ability to operate the device continuously. ('109, Col. 13, lines 8-14) Thus it would be obvious to one of ordinary skill in the art to modify the device of Svedman by attaching a collection canister to the second end of said fluid connection as taught by Henley to facilitate continuous operation of the device.

With respect to **Claim 6:** Svedman teaches a device comprising screen means 11 for placement within a wound bed, sealing means 10 adhered over the screen means and thus also over the wound bed. Conduit 12 fluidly connects said screen means 11 to a vacuum source. A fluid compositional sensing device 16 sensing temperature (interpreted herein as a fluid compositional characteristic in that a temperature increase signals the presence of bacterial infection which is a change in composition), is placed in the conduit 12 (i.e. between the screen means and vacuum source) and connected to the regulator member 15 of supply conduit 12 which connects said screen means and sensing device 16 with the vacuum source. (Col. 3, lines 39-42)

Svedman teaches a fluid removal connection 13 but does not explicitly teach that the connection 13 is to a collection canister. Henley teaches a wound treatment apparatus with a

With respect to **Claim 7:** The combined teaching of Svedman and Henley does not teach that the sensor is embedded in the screen means 11. Scherson teaches an oxygen- producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Scherson teaches that the sensor can regulate the flow of oxygen to the bandage. Similarly, it would be obvious to one with ordinary skill in the art to embed the sensor taught by the combined teaching of Svedman and Henley in the screen means to effectively monitor the drainage fluid composition or parameters to detect the onset of infection at the wound site.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Henley et al ('109), as applied to claims 5, 6 and 10 above, and further in view of Fleischmann ('767).

With respect to **Claim 8:** Svedman teaches a sensing device and a sealing means but does not teach that said sensing device is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 (fig. 1 and col. 4, lines 62-64). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to modify the sensor and sealing means taught by the combined teaching of Svedman and Henley such that the sensor is disposed on the sealing means to detect infections in the atmosphere near the wound area as taught by Fleischmann.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Henley et al ('109), as applied to claims 5, 6 and 10 above, and further in view of Parker et al ('391).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Henley et al ('109), as applied to claims 5, 6 and 10 above, and further in view of Fleischmann ('767).

With respect to **Claim 8:** Svedman teaches a sensing device and a sealing means but does not teach that said sensing device is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 ('767, Fig. 1 and Col. 4, lines 62-64). Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to modify the sensor and sealing means taught by the combined teaching of Svedman and Henley such that the sensor is disposed on the sealing means to detect infections in the atmosphere near the wound area as taught by Fleischmann.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman ('441) in view of Henley et al ('109), as applied to claims 5, 6 and 10 above, and further in view of Parker et at. ('391).

With respect to **Claim 9:** Henley discloses a canister and a sensing device outside of the canister but does not disclose a sensing device for sensing infections located in the canister. Parker teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col.5, lines 16-21) to monitor parameters of the fluid collected. This provides additional and more accurate means for detecting infection at the wound site as taught by Parker, therefore it would be obvious to one with ordinary skill in the art to provide the

invention of the combined teaching of Svedman and Henley with the sensing probe of Parker inside of the canister taught by Henley.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

January 29, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER